

CLINICAL ENGINEERING

Quality Assurance

Type I Materiel Complaint - NSN 6530-00-782-6503; Table Top Sterilizer; Spectronics Corp. Model 750-G

Reference AFMLO QA message 6102-0009 (O 112001Z Apr 96). Referenced message requires suspension of subject item from issue and use. During maintenance procedures, a sterilizer exploded due to a clogged drain line. Failure is inability of relief valve to relieve chamber pressure. An 8 ounce piece of the door lock mechanism was launched, missed personnel, ricocheted off furniture, coming to rest 25 feet away from the sterilizer. This particular sterilizer was not equipped with a retrofit kit which was offered by Spectronics in 1984 to address this problem. Remove any Spectronics sterilizer model 750 from service until maintenance personnel verify that the retrofit kit is properly installed and the unit is safe to operate. Maintenance personnel should not proceed unless they have a copy of Spectronics' August 8, 1984, letter with attachments. This model was discontinued in 1984 and there are no retrofit kits currently available from Spectronics. This Type I Medical Materiel Complaint is currently under investigation by the Defense Personnel Support Center (DPSC). Disposition instructions will be provided when available.

Type III Materiel Complaints - Information Exchange

A summary of the most recent medical materiel complaints involving medical equipment is listed below. This summary is provided for information only. Please note the complaints **are not validated**. They do not constitute a recall, nor do they require you to perform the sort of inspection and reporting associated with equipment hazards. If you have experienced a similar problem locally, please submit an SF 380 in accordance with AFMAN 23-110, Vol. 5, Chap. 19. It is important that we receive documentation of equipment problems since severity and impact of a materiel defect is frequently judged by the number of separate complaints received.

Translating Table, Ophthalmic, MARCO Ophthalmic Inc., TS-1. **Complaint:** An activity reports that the table top was becoming increasingly difficult to move longitudinally. A long scrape was also evident just under the table top that paralleled the table range of travel. This table supports a Vision Tester, Auto-Refractometer and a Non-Contact Keratometer. The table top rail (p# 72-2804-1) roller surface had bent from a 90 degree angle to about 120 degrees. The difficulty in table top travel and the scrape were a result of the bent rail. With the rail removed, a three foot groove worn longitudinally inside the aluminum rail was discovered. After further inspection, it was noted that most of the equipment weight (136 lb total) was distributed towards the patient's side of the table (opposite the side of the defective rail). This imbalance put constant upward pressure on two steel rollers on which the rail traversed. These rollers (Bishop-Wisecarver p# W-2) have two "V" shaped surfaces, one of which over time wore the groove into the rail. The rail wore to the point that it eventually began to bend. If not identified in time, there is a potential for the table top to tip over, dumping the equipment to the ground.

**Safety Alert --
Anesthesia Units, MDC 10134,
Narkomed 2A, 2B, 3, 4, North
American Drager**

Reference ECRI *Health Devices Alerts* Number 1996-A13, 29 March 1996, Accession No. A2991. ECRI reports that a Narkomed 2A system produced a prolonged inspiratory phase of the breathing cycle. North American Drager acknowledges that, if the MJV-2 Clippard valve in the ventilator in the above units manufactured prior to Sept 1991 is not lubricated according to the manufacturer's recommended annual maintenance schedule, it may become stuck in the inspiratory phase. All facilities should verify that the MJV-2 Clippard valve of any of the specified units have been lubricated annually. The proper procedure for lubricating the valve is provided in a Field Service Procedure (P.N. SP00062, Rev B, Mar 18, 1994) which may be obtained from the manufacturer. If the Clippard valve has been observed sticking, the valve case assembly should be replaced. For further information or to obtain the Field Service Procedure, U.S. customers should contact North American Drager Technical Service at (800) 543-5047; customers outside the U.S. should contact their local Drager distributor.

**Safety Alert --
Ventilators, Intensive Care,
MDC 17429, Bear 1000,
Allied Healthcare Product Inc.**

Reference ECRI *Health Devices Alerts* Number 1996-A14, 5 April 1996, Accession No. A3003. ECRI reports there are potential compatibility problems if datum is transferred from the RS232 data ports to a third-party monitoring system. This condition occurs only with third-party monitoring systems; the use of the Bear Graphic Display is not affected. Allied Healthcare contacted ventilator owners by Medical Device Advisory (50000-10661) dated April 1996, informing customers of the problem. Using facilities should verify that you have received the advisory from Allied Healthcare. If you intend to connect your Bear 1000 ventilator to a third-party monitoring system through the RS232 port, contact Bear Medical Technical Support at (800) 232-7633 in the U.S. or at (909) 788-2460 outside of the U.S. for further information.

**Safety Alert --
Ventilators, Transport, MDC 18098,
Bird Avian Ventilator,
Bird Products Corp.**

Reference ECRI *Health Devices Alerts* Number 1996-A14, 5 April 1996, Accession No. A3004. Part Nos.: 15304, 15345, 15345A, 15345C, 15345J, 15345L, 15345S, 15365, 15365A, 15365C, 15365J, & 15365S. ECRI reports that Bird Products Corp. has determined that an electrical fault could occur while the ventilator is in use. In the presence of an elevated O₂ environment, which can occur when the unit is operated with an O₂-enriched gas supply, the probability of combustion is greatly increased. This occurrence could subsequently cause the device to stop operating or go into undetermined operating states. To prevent this occurrence, the use of all Avian ventilators must be discontinued

immediately. Bird Products informed customers of the potential problem by Urgent Safety Alerts dated April 1 or 2, 1996. Bird Products will provide customers with further information by April 15, 1996. **Using facilities should stop using all Avian ventilators immediately.** For further information, contact Bird Products Technical Support Department at (800) 760-2473, (619) 778-7200, or by fax at (619) 778-7274. (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

Food and Drug Administration (FDA) Recalls/Alert Notices

Attachment 2, paragraph 1, provides information on FDA medical equipment recalls and alerts. Personnel from clinical engineering, biomedical equipment maintenance, quality assurance, and safety should follow the guidance provided to ensure the effective maintenance and management of medical equipment. (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

Medical Equipment Management

Shared Procurement Equipment Items Currently Available

AFMLL 06-96, Attachment 1, pages 4 and 5, contains a list of all current Shared Procurement contracts and optional contracts available through the Defense Personnel Support Center (DPSC). If you plan to order any of these items for your facility, use the specific ordering instructions and overall program guidance contained in AFMLL 4-96, pages CE-4 and CE-5. (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

“Piggyback” Contracts Currently Available

AFMLL 08-96, Attachment 1, pages 1 and 2, contains a list of all current “piggyback” contracts currently available through DPSC. These contracts will allow facilities to “piggyback” requirements onto existing orders placed for specific quantities. Many of these contracts are designed to buy large quantities at reduced prices, and are written with the option of buying additional quantities at the same price. The list includes available quantities and “Order By” dates. To order, send your requisitions to DPSC (using the MILSTRIP process), Attn: Mr. J. Gallagher/DPSC-MQA, and reference the contract number (from the listing) in the notes section. (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

JEFFREY W. COOPER, Colonel, USAF, MSC
Chief, Air Force Medical Logistics Office